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NATIONAL DRUG POLICIES AND PRACTICES AND THE ROLE PLAYED BY TRANSNATIONAL CORPORATIONS IN SELECTED AFRICAN COUNTRIES*

A Technical Paper

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Preface

This report presents the findings of a consultancy study undertaken on behalf of the Joint ECA/CTNC Unit on TNCs with the aim of identifying, while giving particular focus on the role played by pharmaceutical transnational corporations, major problems, difficulties and opportunities faced by the developing countries of the African region in their efforts to move towards self-reliance in pharmaceuticals.

The report approaches its subject matter by presenting first fundamental questions and measures which, according to current knowledge, are considered to be basically relevant to developing countries as a whole. This is then followed by a closer view of the situation in six selected African countries through an overview of current drug policies and practices undertaken by each country with emphasis on measures which are unique to each country and which are likely to provide lessons for other countries. The six countries selected for gathering empirical data for the study are Ethiopia, Kenya, Tanzania, Sudan, Egypt and Ghana.

1. Summary of findings and recommendations

(a) Summary

The main points that have emerged from the present study which had used six selected countries for examining the pharmaceutical supply system and the role played by transnational corporations in Africa are that:

(i) The pharmaceutical supply system of developing countries is characterized by a low level of development in which lack of adequate policies and management mechanisms for an integrated development of pharmaceutical sector activities continue to burden such countries with many basic problems, including inadequate coverage of the majority of their populations with essential drugs required for primary health care, over expenditure of meagre financial resources on drugs, low indigenous production capability and dependence on imports, lack of a rational system of product selection and usage in public sector procurement, and lack of effective policies and regulatory mechanisms for controlling the proliferation of pharmaceutical products in both public and private sector markets through their inappropriate promotion by transnational corporations.

(ii) In terms of moving towards self-reliance in pharmaceuticals through an integrated development of all pharmaceutical sector activities, Egypt appears to have attained the highest stage of development in Africa. Policy decisions and programmes cover the whole pharmaceutical supply system including procurement, distribution, domestic production, prices, quality control, promotion practices, foreign investment, and exports.

The domestic industry composed of 13 enterprises has been able to meet more than 80 per cent of the country's total demand for drugs in 1979 alone. Public sector firms (7 formulation plants and one enterprise producing pharmaceutical chemicals in bulk) contributing 71 per cent of this demand have been able to lead foreign suppliers and their local subsidiaries in all major therapeutic markets for specialities.

(iii) While Egypt's public sector enterprises are characterized by a long tradition of research and development and an effective exploitation of local resources, the production of raw materials is still in sufficient and varying portions continue to be imported.

(iv) As is the case with the majority of African countries the pharmaceutical supply system in Ethiopia, Kenya, the United Republic of Tanzania, the Sudan and Ghana is characterized by a low level of development whereby:

(v) Low domestic pharmaceutical production capability continues to make these countries largely dependent on imports to meet their pharmaceutical requirements.

(vi) Existing policies and practices are inadequate for ensuring drug quality, efficacy, safety and economy in both public and private sector markets.

(vii) Transnational corporations continue to dominate the local market with a large variety of differentiated products.

(viii) Absence of effective public sector product selection, procurement and distribution system, inappropriate drug promotion and marketing and irrational drug usages throughout the health service system are leading to over-expenditures of meager financial resources.

(ix) All five countries face an acute shortage of trained manpower for manning their pharmaceutical supply systems.

(b) Recommendations

As a first step for moving towards the development of an adequately developed pharmaceutical supply system, the following could be considered as priority areas requiring appropriate action by the countries surveyed under the present project as well as others standing at a similar level of development, excepting Egypt.

(i) The establishment of a unified national plan allowing an integrated development of all components of pharmaceutical sector activity.

(ii) Pharmaceutical legislation and regulatory control aiming at ensuring drug quality efficacy, safety and economy, and in particular;

- limited product registration using the certification scheme recommended by the World Health Organization with the aim of reducing the range of differentiated products on the market.

- application of effective regulatory measures for ensuring drug quality through the implementation of the W.H.O. recommended Good Manufacturing Practices in industry including sampling of drugs and their analysis at a centralized national laboratory.

- adequate control of pharmaceutical pricing at manufacturing, wholesaling and retailing levels to check excessive profit margins on drug sales.

(iii) Establishment of an effective system of product selection (using the W.H.O. model list of essential drugs to guide public sector pharmaceutical procurement as well as domestic production.

(iv) Establishment of an efficient system of pharmaceutical procurement and distribution in the public sector which ensures that purchases are based on a list of essential drugs, an efficient tender system, proper inventory control and adequate storage and transport facilities to ensure the timely delivery of needed supplies in sufficient quantities and to rationalize pharmaceutical expenditures.

(v) Increasing national capability in the management and regulation of pharmaceutical sector activities in terms of providing the necessary manpower inputs through expansion of training facilities and programmes.

(vi) Establishment of the necessary policy directives and mechanisms to allow the domestic pharmaceutical industry to participate meaningfully in the development process.

(vii) Increasing national capability through the application of individual and collective efforts supported by the United Nations in dealing with basic problems related to foreign investment, technology, patents and trademarks.

2. Basic problems of universal concern

To attain WHO's Global Strategy of Health for All by the Year 2000, there still appears to be, particularly in the developing world, an urgent need to establish and implement effective policies and mechanisms, at the national as well as regional and global levels through action programmes of international co-operation, for ensuring the rational and effective delivery of pharmaceutical services.

The fact that large segments of the population of the developing world have no access even to the most essential drugs while many developing countries are wasting their meagre resources through over expenditure on drugs without having the capability to obtain the most suitable drugs under the most favourable conditions has given rise much debate in numerous international meetings in which developing countries have expressed their serious concern about these and other grave problems presented by the pharmaceutical supply situation in their countries and have called for action programme of international co-operation for the establishment of effective policies and mechanisms for:

(a) Controlling the abusive practices of pharmaceutical transnational corporations which are creating serious obstacles to be rational and effective delivery of pharmaceutical services;

(b) Providing an appropriate list of essential drugs and vaccines for disease control and primary health care together with adequate technical information on them to ensure their optimal utilization including cost/benefit considerations;

(c) Controlling the quality, efficacy and safety of both imported and locally produced drugs;

(d) Providing a suitable system for the procurement, storage, distribution and local production of pharmaceutical products in order to reduce costs and to forestall sudden shortage of essential drugs and vaccines;

(e) Reviewing available manpower resources in each country and evaluating manpower training needs, particularly those concerned with the management, production, quality control, procurement and distribution of pharmaceutical and medical supplies;

(f) Planning and implementing activities and identifying problem areas for co-operation through the collaboration of United Nations Agencies.

However, due note must be taken of the fact that the unsatisfactory pharmaceutical supply situation in the developing countries is characterized by such widespread and complex problems that the task of gearing the pharmaceutical supply systems of such countries in the right direction is no less than a truly formidable task which will need to be tackled on a broad front and in which the limited national capabilities of the developing countries will need to be strengthened through economic and technical co-operation among countries supported by international organizations.

Notables steps taken in this direction, particularly in terms of co-operation at the international level are:

- the Lima Declaration and Plan of Action in the pharmaceutical sector; and

- the Action Programme of Economic and Technical Co-operation among Developing Countries in the pharmaceutical sector resulting from the resolution of the 1976 Colombo Conference of Non-Aligned Countries, which WHO, UNIDO and UNCTAD are working together to implement.

3. The role of pharmaceutical transnational corporations

(a) Production and sales volume

About 90 per cent of the world output of pharmaceutical products, estimated in 1976 at about $ US 50 billion at manufacturer's prices, produced by some 100 major transnational corporations. Developing countries (excluding Mexico, Brazil and India) accounted for only 5 per cent. The share of these developing countries in world output by the year 2000, is estimated to stand at about 17 per cent, thus falling far below the 25 per cent target called for in the Lima Declaration.

Table 1: World trade in pharmaceutical products (1974)

	Imports (millions of $ US)	Percentage of world imports	Exports (millions of $ US)	Percentage of world exports
World trade	6,042		5,910	
Developed countries	4,052	67.1	5,486	92.8
Developing countries	1,990	32.9	424	7.2

Table 2: Drug sales of major transnationals in 1974 (millions of $ US)

	1970 Value	Percentage	1974 Value	Percentage
Total sales (developed countries)	18,633	100	34,001	100
Sales of leading 10 transnationals	4,987	27	9,498	28
Sales of leading 20 transnationals	7,748	42	14,561	43
Sales of leading 30 transnationals	9,249	50	17,682	52

Sources:

WHO background document A31/Tech. Discussion/1, 1978; p. 9;

United Nations Centre on Transnational Corporations, Report on transnational corporations and the pharmaceutical industry, 1979, p. 19;

The growth of the pharmaceutical industry in developing countries; problems and prospects, UNIDO, New York, 1978.

While the share of each transnational varies from country to country some 100 corporations from the industrialized countries control 70 to 90 per cent of the pharmaceutical market in the third world. Within the African continent only Egypt has strictly limited foreign participation with the domestic industry having achieved a relatively advanced stage of development.

(b) Marketing practices

Pharmaceutical transnational corporations are still able to dominate the international market with a bewildering array of trade mark or brand-name drugs. The variety of names may range from some 2,000 to 80,000. Such a system forms the basis of the drug industry's intensive promotional activities. The goal of each transnational's promotional programme is to gain and maintain market dominance for its products through the creation of strong and lasting brand-name preferences among prescribers and the consumer public without simultaneously generating sales for the lower priced rival products. According to United Nations findings, approximately 20 per cent of all drug sales by transnationals goes for promotion, which in the United States alone amounted in 1978 to $ US 1.9 billion on total ethical drug sales of $ US 9.34 billion.

While competition exists and is concentrated in multiple source generic products, the brand name system shields the major corporations from competition and enabling them to dictate the prices of their products through often unjustified claims of superiority over rival products. This has led in general to excessive price increases, overconsumption of and over expenditure on drugs many of which are not relevant to the priority health needs of developing countries. Under such circumstances, developing countries, particularly those which depend almost totally on imports to meet their pharmaceutical needs, cannot afford the luxury of buying many different drugs supplied by transnationals (most of which are expensive brand-name products),

for preventing or treating one and the same disease. They could benefit greatly from shopping around, using a list of essential drugs based on public health needs, disease patterns and available economic resources.

Such an approach would naturally imply, among other things:

- Elimination of imitative drugs for which adequate thereapies already exists on the market;
- Elimination of ineffective drugs including irrational combinations of unproven efficacy;
- Elimination on the basis of toxicity characteristics, etc.

4. Basic components of national drug policies and management mechanisms

The basic components of national drug policies and management mechanisms of a full developed pharmaceutical supply system are many and vary from one country to another. Their full implementation is, however, beyond the capabilities of developing countries where only limited resources are available. In many developing countries, the following could be considered as priority areas requiring appropriate action:

(a) Drug legislation and regulatory control

Drug legislation and control must, particularly in developing countries be carefully adapted to local needs, priorities, and political and socio-economic conditions, taking into account enforcement possibilities. As a first step towards regulating drug control, legislatory provision should be made allowing the establishment of an appropriate section within the Ministry of Health responsible for registration and surveillance of marketed drugs and inspection and licencing of establishments for imports, distribution and local manufacture of drugs.

To be effective, a system for implementing drug legislation requires adequate government resources including finance, managerial competence and co-ordination of activities particularly when various government agencies are involved in the enforcement of different aspects of drug legislations. In view of the complexities of the problems related to drug control and the limited capabilities of developing countries, the latter would be wise to reduce their drug regulatory burdens through TCDC and by making good use of the various efforts already undertaken by WHO in this field. 1/

1/ Examples include:

(a) Certification scheme on pharmaceutical products moving in international commerce. WHO chronicle 1977, vol. 31, No. 12

(b) Good practices in the manufacture and quality control of drugs: WHO Officials Records, No. 226, 1975.

(c) Evaluation of safety and efficacy: WHO Tech. Rep. Series, No. 482, 1971, and No. 569, 1975.

(d) Information on drugs through WHO drug monitoring programme: WHO Techn. Rep. Series, No. 498, 1972.

In any case the main aim of such legislation and control is to ensure as far as possible that:

(i) All drugs, whether imported or locally produced are of adequate quality;

(ii) New drugs are adequately tested and their efficacy and safety evaluated;

(iii) Full information, including undesirable effects, is provided to prescribing physicians;

(iv) Consumers are protected from false and misleading information, unsupported therapeutic claims and other abusive business practices of commercial pharmaceutical enterprises.

(b) Product selection based on a restricted list of essential drugs for the public sector

Experience in both developing and developed countries where limited drug lists and formularies are successfully used, for instance in hospitals, supports the notion that the number of drugs required is small. The main advantages of limited drug lists, particularly in developing countries with limited financial, technological and managerial resources, are:

(i) Reduction in the number of drug products to be purchased, stored, analysed and distributed;

(ii) Improvement in the quality of drug utilization, management, information and monitoring;

(iii) Price decrease through large purchase via tender;

(iv) Stimulation of local pharmaceutical production.

However, the preparation of a model list of essential drugs and vaccines applicable to each and every developing country is not considered possible because of divergencies among countries in patterns of diseases, demographic and environmental factors including nutritional status, skilled manpower and financial resources. The ultimate responsibility for identifying essential drug lists required to meet priority needs based on national policies rests on the countries concerned.

Continuing with its efforts in assisting developing countries in this area, WHO has proposed guidelines for establishing a list of essential drugs, suggestions for drug information and educational activities and a model list of essential and complimentary drugs which can furnish a basis for countries to identify their own priorities and to make their own selections. 2/

2/ WHO Expert Committee on the Selection of Essential Drugs; WHO Technical Report Series, No. 615, 1977.

Such a list aims basically at meeting the needs of the primary health care units of the country, in terms of widely prevalent deceases and preventive health care. Second-line drugs and beyond are those used in severe cases not responding to first-line drugs and for specialized care in which quantities required are small. It is to be noted however that two strong forces, the drug industry and medical practitioners (particularly in the private sector), still oppose the effective application of such a restricted list of drugs. A case in point observed during the present study missions is the fact that Kenya, Ethiopia and the United Republic of Tanzania have expended much effort in formulating such basic drug lists but their effective implementation is yet to be achieved.

(c) Procurement on a national or possibly regional level through TCDC

In many developing countries with limited financial and managerial capabilities for meeting national drug demands, priority is given to meeting public sector needs through the establishment of a centralized procurement system from multiple sources on a national or possibly regional basis through international co-operation. Ethiopia, Kenya, the United Republic of Tanzania, the Sudan, Egypt and Ghana are among such countries that have already established a centralized procurement agency on a national level for the public sector.

The primary strategy here is to find cost-effective ways of purchasing drugs. Procurement procedures are based on tenders, and in order to reduce unit price, large orders are placed annually or at longer intervals for products of long shelf-life and whose international price is stable. In all cases, it is necessary to ensure proper delivery, product quality and reliable drug information.

Many of the procurement problems faced by developing countries, such as lack of marketing intelligence, lack of managerial skills especially in price/quality evaluation, quality assurance, etc., could be resolved through technical co-operation among developing countries and with the help of international organizations such as WHO, UNIDO in the transfer of appropriate technology, information, managerial skills, and so on. TCDC in collective drug procurement could improve bargaining power and stimulate competition among suppliers leading to favourable conditions of drug purchase by developing countries.

(d) Distribution

In many developing countries, including those involved in this study, drug distribution involves both the public and private sector. In the public sector, a central State Agency under the Ministry of Public Health is responsible for procuring and distributing all pharmaceutical and medical supplies to public sector hospitals, health centres and dispensaries throughout the country. The private sector distribution system may consist of a central pharastatal agency as in the United Republic of Tanzania, or private importers and wholesalers, as in Kenya and Ethiopia, supplying private hospitals, clinics and retail establishments.

In order to achieve maximum effectiveness, the main points to be considered in planning or re-organizing a State distribution system which is to include central, intermediate and peripheral storage facilities are the following:

(i) Availability of products considered to be most suitable in the light of health priorities and the professional qualifications of the persons responsible for their application;

(ii) Adequate storage facilities at all points of the distribution chain;

(iii) Adequate inventory control to avoid or forestall sudden shortages;

(iv) Adequate transport facilities;

(v) Packing materials;

(vi) Quality surveillance, particularly in relation to deterioration because of long transport under adverse climatic conditions and reductions;

(vii) Provision of adequate managerial skill through education and regular training of staff;

(viii) Drug utilization surveys to serve as an aid in the determination of such matters as absolute and relative efficacy and safety of drug therapy; benefit/risk and cost/effectiveness; overuse, underuse or misuse of single drugs or therapeutic classes etc.

(e) Local production based on essential drug lists

Pharmaceutical production can be divided into three distinct stages:

(i) Repacking of finished products bought in bulk;

(ii) Formulation from half finished intermediates or raw materials;

(iii) Production of raw materials and intermediates.

Entry is easiest at the stage of repacking of finished products and most difficult at the stage of producing raw materials and intermediates. The main constraints to the growth of the pharmaceutical industry in developing countries are inadequate technology, lack of qualified manpower and supporting infrastructure, high cost of imported products and materials, scarcity of financial resources and lack of a well defined policy for promoting local production of pharmaceuticals. However, lack of concern shown so far by transnationals for the priority health needs of developing countries, the continuous proliferation of and rise in the cost of drugs and excessive dependence on imports for meeting the drug supply needs of the population are leading many developing countries to make effort to establish domestic drugs manufacturing facilities. Such efforts are primarily aimed at avoiding unforeseen supply shortages through imports, lowering the cost of drugs and providing essential drugs which are appropriate the countries' real needs.

Accordingly, developing countries with limited capabilities would, as a start, find it easier to establish local facilities for repacking finished products bought in bulk according to a priority list of essential drugs. Such products are freely available from multiple sources and costs could be reduced through bulk purchase on a tender basis. The technology for formulation is relatively simple and could be acquired, using the TCDC concept from a number of developing countries that have already gained a higher level of sophistication in pharmaceutical production technology.

However, as production expands towards greater sophistication developing countries would face growing constraints in terms of money, skills, technology and quality control which they may not be able to cope with individually.

Ideally therefore, the development of local pharmaceutical production should proceed sequentially, beginning with the simple activities of repacking and formulation and steadily moving towards more complex activities, requiring transfer of technology via TCDC and from industrialized countries through co-operation and co-ordination by the international organizations, particularly UNIDO and WHO.

(f) Quality guarantees at the national or regional level via TCDC

Although it is generally recognized that the primary responsibility for the guarantee of drug quality, efficacy and safety rests on the drug manufacturers themselves, the ultimate responsibility for ensuring the consumer public that the manufacturers has observed good manufacturing practices for drug quality, efficacy and safety rests with the Governments concerned.

Developed countries are able to apply stringent control measures through adequate pre-market screening and post-market surveillance to ensure drug quality, efficacy and safety. Many developing countries, including those involved in this study assignment, lack the resources for performing rigorous pre-market screening tests and elaborate post-market surveillance produdures. Consequently, such countries could, as a start, adopt the following strategy for drug quality:

(i) Effective use of the Certification Scheme recommended by WHO. This requires that the product is fully available on the market of the country of origin and that the manufacturer is subject to inspection at regular intervals to ensure that adequate manufacturing practices and quality control procedures are followed. The Scheme also allows the importing country to obtain additional quality control information including the results of control analysis on a specific batch from the health authorities of the exporting country;

(ii) Effective application of the Good Practices in the Manufacture and Quality Control of Drugs recommended by WHO;

(iii) Sampling of incoming drugs, their analysis and exchange of information on products through TCDC;

(iv) Limited product registration to reduce the range of products and therefore decrease the quality of drug utilization, management, information and subsequent monitoring. Developing countries could also take advantage of the following WHO contributions:

- Basic tests for drugs to confirm the identity and basic efficacy of drugs;

- Publication and distribution of a quarterly bulletin providing information on the status of both new and old drugs and the establishment of an international monitoring system for adverse reaction to drugs;

- Publication of international registration and quality standards.

(g) Information and manpower training via TCDC and WHO assistance

Various types of information on drugs are needed by prescribers and consumers for optimal use. In many developing countries most of the information on drugs is supplied by the pharmaceutical firms in the form of booklets, pamphlets and visits by agents. Such information is often biased and commercially oriented. Ideally therefore, importing countries themselves should control promotion and provide the required information to prescribers and consumers.

However, many developing countries, including these upon which this study has focused, do not have sufficient capability by themselves to assume this responsibility fully. Technical co-operation in the adequate transfer of drug information, supported by WHO, would be the best approach for solving this problem. WHO has already provided a model drug information sheet, which developing countries could adjust to their individual needs.

In developing countries the need for education and training on the proper use of drugs for prescribers, disponsers and consumers is recognized. Education should be continuous throughout the entire professional life of health workers using all available means. Such countries should, in addition, attempt to improve the situation further through co-operation of the regional and international levels.

5. The Role of international organizations

The main strategies and activities pursued by WHO and other United Nations agencies for strengthening the national capabilities of developing countries for establishing an adequate pharmaceutical supply system to meet the needs of their populations may be summarized as follows:

(a) Selection of essential drugs

A basic strategy recommended by WHO and UNIDO is that of providing a restricted list of essential drugs of proven quality and safety, which meet the broad range of health care needs most economically. WHO has devised a model list of essential and complementary drugs for individual countries to identify their own priorities and make their own selections. 3/

(b) National and regional drug procurement

Several United Nations agencies are involved in assisting developing countries in obtaining quality drug supplies freely or at reasonable cost through national or regional agencies. WHO and UNHCR operate free supply services. UNICEF is reported to be able to buy generic drug products in bulk and resell them to developing countries at 25 to 50 per cent of their market price. 4/

WHO's action programme on essential drugs for 1978 includes TCDC in the bulk purchase of essential drugs at reduced prices. Also through its dialogue with the pharmaceutical industry, some major transnationals have offered to place some highly useful drugs at the disposal of the most underpriviledged countries under special conditions and prices with WHO acting as an intermediary and co-ordinator. The result of this particular effort is still being awaited.

The action programme for 1979-80 includes global activities involving centralized imports by the State and collaboration with other States through TCDC; and developing policies and legislation on the transfer of appropriate technology and foreign investment for local industries.

Regional activities for Africa involve planning and implementation of activities and identifying problem areas for co-operation through TCDC in the selection of essential drugs; quality assurance; joint procurement and price information.

Country surveys include establishment of alternative strategies for TCDC in bulk purchasing (procurement, storage and distribution and discussion of the possible structures and their relation with WHO, UNICEF, UNDP and ADB; review of current legislation; review and approval of the draft list of essential drugs; review of available manpower resources and evaluation of need for their upgrading; role, organization and location of quality control laboratories; etc. 5/

3/ Ibid.

4/ United Nations Centre on Transnational Corporations; Report on Transnational Corporations and the pharmaceutical industry, 1979; p. 98-99.

5/ Desk study at WHO-AFRO, Brazzaville, 25 and 26 June 1979.

(c) Establishment of national or regional pharmaceutical production facilities

Individual Governments that have reached a sufficient level of socio-economic development for promoting the establishment of local or regional pharmaceutical production are being assisted by WHO in collaboration with UNIDO.

WHO's action programme on essential drugs for 1979-1980 includes global activities involving developing local industries in line with the socio-economic conditions of each country using small-scale appropriate technology and traditional herbs. WHO's outside activities relate to dialogues with UNCTAD, UNDP, ADB, UNICEF, UNIDO, OAU, the World Bank and the pharmaceutical industry.

UNIDO has been instrumental in promoting local production capabilities through the establishment of regional centres to pool resources for further development. UNIDO has conducted various feasibility studies and is preparing for global consultations on the pharmaceutical industry aimed at establishing a dialogue between the industrial and developing countries.

UNIDO is also assisting member States in the development of the traditional medicines industry and in the transfer of technology in this field.

(d) Other activities 6/

WHO is the leading United Nations agency involved in providing assistince to developing countries in the following areas:

(i) Quality control:- Among the most important programmes in this area are the Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, and the Good Practices in the Manufacture and Quality Control of Drugs;

(ii) Standardization of information on drugs. International non-proprietary names (INN) are published annually;

(iii) Publication of a model drug information sheet;

(iv) Devising basic tests for drugs. These are simple tests designed to confirm the identity and basic efficacy of drugs;

(v) Publication and distribution of a quarterly bulletin providing information on the status of both new and old drugs and the establishment of an international monitoring system for adverse reaction to drugs;

(vi) Publications on international registration and quality standards;

6/ WHO Official Records, No. 209, 1973, p. 14.
WHO Technical Reports Series, No. 563, 1975.
United Nations Centre on Transnational Corporations, Report on transnational corporations and the pharmaceutical industry, 1979, p. 101-104-5.

(vii) Research and development:- WHO is co-operating with the pharmaceutical industry and non-profit laboratories in developing new drugs for tropical diseases; clinical evaluation of new drugs; and training scientists and technicians;

(viii) WHO is designating regional research and training centres for the study of medicinal plants. One such centre already established at Rome, Italy, is involved in training African scientists, establishing botanical gardens for medicinal plants and staging laboratory and clinical trials using traditional therapies. WHO and UNICEF are collaborating in this project;

(ix) UNIDO is assisting in the development of an integrated pharmaceutical industry including production, packaging and utilization of medicinal plants.

6. Pharmaceutical supply situation by country

(a) Ethiopia

Ethiopia is one of the least developed countries in the world with a low GNP per capita estimated at less than $US 100, and illiteracy rate of over 90 per cent, prevalence of preventable communicable and other diseases, poverty and poor state of public health services whereby 80 to 90 per cent of the country's population, particularly these living in rural areas, have long remained outside the reach of modern health care. A few indicators follow:

Table 3: Health facitities and personnel

Category	1974 Country total	1972 Country total	1976 Addis Ababa	1976 Country total	Ratio - Population per category
Hospitals	38	85	13	84	332 000
Health centres	-	93	-	106	263 000
Health stations	120	649	16	1 010	22 600
Beds (total	3 300	8 415	2 499	8 623	3 200
Medical doctors	100	374	164	347	80 400
Health officers	-	213	25	214	130 400
Nurses (all categories)	90	1 162	521	1 221	22 900
Health assistants	70	4 003	1 082	4 374	6 400
Sanivarians	-	241	33	264	105 700
Technicians (Lab & X-Ray)	-	253	126	389	72 000
Pharmacists (all categories)	-	23	23	83	336 000

Sources: Ministry of Health, Comprehensive Health Service Directory, 1976, p. 4-26;

Ministry of Information, Publication on Public Health, 1973, p. 7-31.

Table 4: Health personnel trained locally

Category	1972-73	1973-74	1974-75	1975-76	1976-77	Total
Medical doctors	15	9	-	22	-	46
Health officers	4	36	-	42	14	96
Pharmacists	15	23	6	10	-	54
Nurses all categories	70	139	-	87	268	564
Sanitarians	14	16	-	30	-	60
Health assistants	339	347	-	672	978	2 336
Technicians, Lab + X-Ray	10	29	-	39	50	128

Source: The Ethiopia Statistical Abstract, 1977, p. 237-241.

Table 5: Government expenditure on health

Fiscal year	Millions of $US	Population in millions	Per capita expenditure $US
1973-74	18.70	25.95	0.72
1974-75	20.10	26.58	0.75
1975-76	20.87	27.18	0.77
1976-77	28.41	27.91	1.02
1977-78	30.63	28.64	1.07

Source: Ibid.

According to the Ethiopian Statistical Abstract of 1977, the combined population of the three major towns of Addis Ababa, Asmara and Harar in 1977 was 1,516 322 or 5.3 per cent of the country's total population, while the rural masses accounted for 87.5 per cent of the total. Yet 50 per cent of all beds and 63 per cent of all medical doctors were found in these three towns.

The unsatisfactory pharmaceutical situation and the need for establishing adequate national drug policies and management mechanisms particularly relating to drug legislation and regulatory control, a list of essential drugs, procurement, distribution local production, quality control, information and manpower training was stressed in a series of studies carried out under the Pharmaceutical Affairs Division of the Ministry of Health from 1972 to 1977. 7/

7/ Ministry of Health, Division of Pharmaceutical Affairs, Report on utilization of funds for pharmaceutical supplies, May 1975, p. 1-20; Report on national drug policy, Why and how, Nov. 1977, p. 1-15.

The following features were identified:

(i) Ninety-eight per cent of the country's population has almost no access to modern drugs. Public sector expenditure on drugs in 1973 was shown to amount to only $US 0.05 per capita for 98 per cent of the population while the private sector figure stood at about $US 24 for 2 per cent of the population, living mainly in urban areas.

(ii) The Division of Pharmaceutical Affairs lacks adequate policy guides for implementing effective drug regulatory measures. As a result pharmaceutical transnationals are still able to dominate the country's market with a wide variety of duplicative brand-name products estimated to number about 6,000.

(iii) The list of essential drugs containing 534 items published by the Ministry of Health in 1972 was labelled "advisory" in order to minimize objections by various members of the medical profession against exclusions of personally preferred brand-name products. Undoubtedly many such objections are the direct consequence of the strong pressure of transnationals intense brand drug promotion.

(iv) The Government Central Medical Stores, the sole agency for procuring and distributing drugs and medical supplies to public sector health facilities, has, because of inadequate policy guides, remained unable to apply rational procedures of product selection to ensure optimization of drug expenditure. In addition, lack of a responsible delivery system for drug supplies, coupled with sometimes questionable substitution practices and frequent shortage of essential drugs, has long caused problems in regional and peripheral health facilities.

(v) Although the existence of various categories of health service and different levels of skill is recognized, those drugs appropriate to each level have not been defined.

(vi) Even though estimates indicate that the list of essential drugs needed for peripheral hospitals, health centres and health stations, use would comprise less than 150 items, strong promotional pressures by major transnationals, such as Roche, Sandoz, Ciba Geigy, etc., have led to the stocking of high-priced brand name products in preference to therapeutically equivalent generic drugs. Such influences, coupled with inadequate training of health workers and lack of continuing supervision, have made irrational use of drugs a common phenomenon at peripheral health-care facilities.

However, the Governments present policy to establish a unified national plan for the integrated development of the various components of pharmaceutical activity, although only partially successful so far, has served to co-ordinate and strengthen activities in the public sector pharmaceutical supply system, namely:

(i) The National Drug Quality Control Laboratory, which was previously allowed to operate independently of the Ministry's Division of Pharmaceutical Affairs and on a quasi-commercial basis, is now an integral part of the Division. Previously limited to handling a small range of physico-chemical tests, the Laboratory is now well equipped to perform a wide range of tests except for sterility. Its technical staff include one experienced pharmaceutical analyst who heads the laboratory, two other pharmacists, one chemist heading the texicology section, three texicology senior technicians and two pharmacy students in their last year of training serving the laboratory on part time basis;

(ii) The Pharmaceutical and Medical Supplies Corporation (PHARMACOR) created in 1976, is an amalgamation of EPHARM, the Central Medical Stores and a number of wholesale and retail establishments, nationalized in the same year. While this amalgamation has led to better co-ordination of activities of the Central Medical Stores and EPHARM whereby in particular EPHARM has been able to base its production only on generic lines, thus decreasing the variety of production items from 130 to 80 and to increase its volume of production and sales to a very high level as compared to its performance in the past, it still falls short of achieving the aim of basing procurement and production on an established list of essential drugs;

(iii) Since its nationalization and amalgamation with the Central Medical Stores in 1976, EPHARM has been operated entirely by Ethiopian nationals. The plant is well equipped for producing tablets (including strip packing) capsules, syrups, vials (antibiotics in dry form) injections and ointments (skin and ophthalmic). The plant is managed by a qualified pharmacist; the production section is operated by five pharmacists and various auxiliaries; the quality control section is headed by one chemist, who is assisted by two pharmacists and seven graduates of the Polytechnic Institute of Bahr Dar; and the Research and Development section is headed by one pharmacist with a Masters Degree. The quality control section is well equipped to handle physico-chemical, micro-biological and sterility tests on raw materials through and products. Pyrogen testing is done at the National Central Laboratory and Research Institute;

(iv) Under its present policy of producing only generic items, EPHARM plans to reduce further the variety of products to be manufactured from 80 to 50 in the near future. Another important future plan is the production of intraveneus fluids. A feasibility study is already in progress through bilateral co-operation with Cuba. At present EPHARM's contribution to the country's pharmaceutical consumption is estimated to be about 19 per cent.

As already indicated, Ethiopia is the only country among the group involved in the present study assignment that charges high customs duties and taxes on imported drugs amounting to 43 per cent, consisting of 25 per cent customs duties, 16 per cent transaction tax and 2 per cent turn-over tax. This, coupled with transport and other charges from port of entry at Assab or Djibouti, a 20 per cent margin for importers and wholesalers and 40 per cent for retailers contributes to the high cost of drugs.

The retail price/c.i.f. price ratio for the private sector 2.54. In the case of the public sector, involving the Central Medical Stores the price composition is 16 per cent transaction tax 7 per cent transport and other costs, 2o per cent margin for the stores, 2 per cent turnover tax and about 5 per cent margin at health facility level. This unsatisfactory situation is undoubtedly a serious matter requiring the Government's highest attention.

The need to rationalize drug usage at all levels of the public health service system in terms of cost/effective and cost/ benefit considerations is recognized. Accordingly the tusk of drawing up a restricted list of essential drugs and vaccines for use at each level of service was given to a Therapeutics Committee established in 1976. No such list has appeared so far. This is unfortunate particularly in view of the problems indicated above and the fact that the Committee has had ample time to evaluate and adapt to the country's priority needs the existing National Drug List and a model list worked out by WHO's Expert Committee on the Selection of Essential Drugs.

(b) Kenya

Kenya is, like all the developing countries of Africa, still facing many basic problems in meeting the basic health needs of the majority of its population, particularly those living in rural areas. Public health problems are, in general, tied up with other basic socio-economic problems such as limited economic and trained manpower resources, a low and uneven distribution o of health service facilities and personnel characterized by an disproportionally high concentration in urban areas, bread prevalence of preventable communicable and other diseases, poverty, ignorance, high population increase and limited arable land.

In so far as pharmaceutical services are concerned, the countty still depends largely on imports for meeting its needs and seems to have a long way to go before ensuring that the majority of its population have access to even the most essential drugs required for disease control and primary health care. At the same time, Kenya still lacks a unified national policy for developing the country's pharmaceutical supply system by integrating its various components to ensure the rational delivery of services in terms of economic and health considerations. Instead, Kenya is currently pursuing an "open-door" policy in drugs in which public and private sector drug procurement, distribution and production activities are permitted to develop in an atmosphere that allows free but also unnecessary "cut-throat" competition which, in terms of health, may be undesirable. The situation has, in fact, made Kenya a fertile ground for exploitation by transnational pharmaceutical corporations. As a consequence, the country's market is carrying a large variety of pharmaceutical products whose total number is estimated to be about 8,000. 8/

8/ Based on discussions held at the office of the Chief Pharmacist, Ministry of Health.

According to observations made during the present study mission, the main characteristics of the pharmaceutical situation may be summarized as follows:

(i) Drug legislation and regulatory control

Existing legislation for regulatory control of both imported and locally produced drugs as well as persons and establishments dealing with drugs takes the term of the Pharmacy and Poisons Act, and the Dangerous Drugs Act, chapters 244 and 245, of 1972.

This legislation has given the Minister of Health over-all responsibility for ensuring some regulatory control on drugs, including the power to establish a Pharmacy and Poisons Board to assist him in such activities as registering and licencing pharmacists, wholesalers, manufactures and their representatives (drug detailers), as well as for establishing various categories of poisonous drugs lists. Other than these limited and rather simplistic control procedures, the legislation does not contain adequate provisions for the application of desirable control measures in pre-market screening, post-market surveillance and transnational business practices to ensure drug quality, efficacy, safety and economy. In any case, the Ministry lacks the skilled manpower and other resources to apply such adequate control measures.

Under such circumstances, it would appear that Kenya would be wise to adopt the relatively simple drug control strategy of applying, at least as a start, the Certification Scheme recommended by WHO, and its other contributions mentioned above.

(ii) Quality control facility

Although the need for establishing a national central facility for drug quality control has been recognized by the Government, no such laboratory has materialized to date. In so far as staffing is concerned, the only pharmacist who had received specialized training in quality control in Europe under WHO assistance is serving as an instructor of hospital pharmacy attendants at the Medical Training Centre in Nairobi.

(iii) Product selection: List of essential drugs

In spite of the inadequacies in legislative and regulatory control mechanisms, Kenya has taken a leading position among the countries involved in this study in having been able to formulate a list of essential drugs and vaccines using a similar approach to that taken by the WHO Expert Committee on the Selection of Essential Drugs. The list, prepared and printed on 4 January 1979 by the Ministry of Health, contains 154 items, identified under generic names, and categorizes items to be used at different levels of the health service system (health centres, district, provincial and referal hospitals).

Although the Ministry's efforts in formulating the said List of Essential Drugs are to be commended, it is doubtful that it could be meaningfully implemented as long as existing difficiencies in national drug policy and management mechanisms continue to persist and pharmaceutical transnationals continue to exercise strong influence on Kenya's pharmaceutical supply system.9/

(iv) Procurement, distribution and production

Kenya's pharmaceutical procurement and distribution system involves two competing channels, the public and private sector.

(a) In the public sector, the Central Medical Stores acts as the central government agency for supplying the network of government health-care facilities distributed throughout the country. Similar facilities run by voluntary agencies are permitted to use the services of the Store provided they pay a 10 per cent service charge on purchased supplies. Supplies are purchased via international tender on a 12 months basis and on a "quick" quotation for a three months supplies when unforeseen depletion of stock arises. A tender committee under the Ministry of Health is responsible for reviewing and approving the tender purchase of any item worth up to 40,000 shillings while anything above that has to go to the Interministerial Tender Board. Yet in spite of the fact that all tenders invited by the Medical Stores are supposed to be awarded after being processed and approved by qualified professionals who sit at the Ministerial Tender Board there have been persistent complaints about product selection in the tenders. One of the most difficult tasks faced by the Board is getting prescribing medical practitioners to agree on what products should be ordered. Some physicians are known to demand drugs manufactured by particular firms irrespective of the availability of cheaper and equally effective alternatives. While this has contributed to overstocking of costly imported brand-named products unduely delayed notifications of supply shortages by recipient health institutions continue to force the Medical Stores to replenish such shortages by spending more money through local purchases outside the tender system. Such basic defects in the management of the Medical Stores have led to intense public criticism and even government investigations into the Storesoperations on allegations of corruption and inefficiency. 10/

9/ At the time of issue, the Ministry indicated that "Institutions should make sure that they hold reasonable stocks of the items listed under their category", a policy guide which does not seem sufficiently strong.

10/ Kenya's Weekly Review, 6 July 1979: A prescription for drugs shortages.

(b) In the private sector, importation, distribution and sales promotion is carried out by local agents of foreign firms and the domestic industry itself upon obtaining the necessary business permit from the Ministry of Health. Lack of a rational system of pre-market screening and post-market surveillance to ensure drug quality and efficacy and economy coupled with the fact that finished drugs can be imported free of customs duty 11/ while inputs for the domestic pharmaceutical industry (raw chemicals, packaging materials and equipment) are subject to high tariffs and levies appears to favour the predominance of foreign firms on the Kenyan market while discouraging the development of domestic production. As a result Kenya still depends on imports to meet 3/4 of its pharmaceutical needs having at the same time no mechanism for checking the undue proliferation of inappropriate products on both of its public and private sector markets. 12/

(c) Current structure of the pharmaceutical industry

Kenya's pharmaceutical industry is currently composed of 16 production units which include one joint venture, 8 subsidiaries of foreign firms including one from India and 8 locally owned enterprises. In 1978, all these firms put together were able to meet only 24 per cent of Kenya's needs for drugs. Among them, Dawa (a joint venture between a Yugoslav firm, the Kenyan Government and local businessmen) is by far the largest and most modern plant and was, in 1978, responsible for over a quarter of local production and 11 per cent of total consumption. Six TNC subsidiaries are engaged in the production of a limited number of trade marked brands of their parent companies while one Indian and all the 8 locally firms produce mostly generics. Both foreign and local firms limit their operation to formulation and packaging. Almost all raw materials including packaging materials, machinery and equipment are imported. Good manufacturing practices are applied in the larger firms including Dawa. Two foreign subsidiaries and all local firms operate whth hardly any quality control facility. On the whole, it appears that the government's current strategy for encouraging foreign investment in all sectors through generous incentives and very little regulation as well as encouraging imports of finished drugs through exemption of duties while subjecting inputs for domestic production to high tariffs and taxes (Table II) is serving as a major obstacle to rationalizing Kenya's pharmaceutical supply system. The continued persistence of this major problem in spite of the government's declared aim of making drugs accessible to all who need them and its efforts in establishing a centralized public sector procurement and distribution system together with a standard list of essential drugs in 1979 is made evident by the fact that:

11/ Over the counter products are subject to 30 per cent duty, but in many cases such products manage to side-step the customs duty barrier being imported under a pharmacopeal label.

12/ The variety of products moving on the Kenya market in 1978/79 is estimated to be of the order of 8000.

(i) The absence of any rational system of pre-market screening and post-market surveillance of drugs is continuing to burden the entire Kenyan market with an undue proliferation of duplicative pharmaceutical products, both imported and locally produced.

(ii) Serious problems of product selection at the Central Medical Stores persist in which costly branded products are procured while cheaper alternatives are available, including those manufactured by the local industry.

(iii) The Central Medical Stores is not organized to carry out its duties efficiently through lack of adequate financial and manpower resources as well as total lack of distribution depots and transport.

(iv) In the absence of appropriate government support, as noted earlier, locally owned firms including Dawa in which the Government has made substancial investment, have been forced to operate well below their capacity and sometimes sustain heavy losses. Foreign subsidiaries with local production units are able to overcome tariff barriers by manipulating transfer prices of raw materials imported from their parent companies. The protection of trade-marks by patents 13/ also gives foreign subsidiaries an additional instrument for consolidating their market power in Kenya. Priority areas where further progress should be made include implementation of the already formulated basic drugs list, price and quality control of both imported and locally produced drugs, incentives to domestic producers and their protection from unfair foreign competition, technical manpower training, improvement in the operation and management of the Central Medical Stores and improvement in the Government's current policy on imports.

Table 6: Pharmaceutical availability - some indicators

	1976	1977	1978	Measurement
Population	13.752	14.233	14.732	millions
Health expenditure (government)	-	-	809.380	K.Sh. millions
Pharmaceutical imports	133.4	203.5	248.6	" "
" local production	38.0	50.0	60.0	" "
" exports	17.2	43.9	41.8	" "
" Re-exports	8.8	27.1	22.5	" "
" total consumption	145.4	182.5	244.3	" "
" import/ "	-	-	76.0	%
" local production/ consumption				
- all firms	-	-	24.0	"
- Dawa alone	-	-	11.0	"
Pharmaceutical consumption/ health - expenditure	-	-	30.0	"

Sources: Kenya's National Development Plan (1979-83) Part I.
Discussions at the Industrial Survey and Promotion Centre.

13/ Patent registration is relatively easy to obtain upon payment of modest fee. The patent laws in force are the same as those in the United Kingdom as no change was made after Kenya's independence.

Table 7: Domestic pharmaceutical production units (Kenya)

	Firm	Nationality	Product Range	Level of G.M.P.*	Product lines
1.	Dawa	Joint Venture	Wide	Adequate	Mostly Generics
2.	Sterling	U.S.A.	Limited	"	TNC Brands
3.	Hoechst	West Germany	"	"	" "
4.	Boots	U.K.	"	"	" "
5.	Glaxo	U.K.	"	"	" "
6.	Nicholas	Australia	"	Low	" "
7.	Wellcome	U.K.	"	"	" "
8.	Chemafric	India	Wide	Adequate	Generics & Brands
9.	Cosmos	Kenya	Limited	Low	"
10.	Didy	"	"	"	Generics
11.	P.A.C.	"	"	"	Generics & Brands
12.	M.A.C.	"	"	"	Generics
13.	Elys	"	"	"	"
14.	P.M.C.	"	"	"	"
15.	Intapharm	"	"	"	"
16.	Lab & Allied Equipments	"	"	"	Generics & Brands

* G.M.P. = Good Manufacturing Practice

Source: Discussions at the Chief Pharmacist's Office, Ministry of Health and at the Industrial Survey and Promotion Centre.

Table 8: Customs duties and taxes

Imported Item	Deposits on c.i.f.	Customs Duties on c.i.f.	Sales Tax on c.i.f.
Finished products	25%	-	-
Raw materials	-	20-30%	-
Brown Glass Bottles	100%	30%	15%
Equipment	"	20%	10%
Packing materials	"	33%	8%

Source: Discussion at the Industrial Survey and Promotion Centre and at the Ministry of Health.

(c) The United Republic of Tanzania

According to the third five-Year plan of economic and social development (1976-81), the Government's main aim for the health sector is to encourage the expansion of health services in order to cover the country's rural communities which constitute more than 90 per cent of the total population, while giving more emphasis to preventive health care and to the training of health workers in general and those at village level in particular.

Table 9: Health facilities

	1972	1973	1974	1975	1976	1977
Hospitals	17 126	128	128	128	128	129
Beds	17 697	18 104	18 330	19 400	19 580	19 823
Rural health centres	99	108	130	138	162	181
Beds	2 160	2 358	3 260	3 386	3 722	3 989
Dispensaries	1 501	1 560	1 620	1 736	1 347	1 997
Beds	8 197	8 300	8 420	8 485	8 546	8 676

Table 10: Health manpower

	1972	1973	1974	1975	1976	1977	1981 a/
Medical doctors	494	532	603	637	683	727	3 000
Assistant medical officers	140	140	160	160	193	223	
Medical assistants	335	405	495	605	770	930	1 200
Rural medical aids	578	621	700	790	1 043	1 393	2 800
Health auxiliaries	290	325	370	410	455	400	1 793
Nurse midwives, Grade A	877	934	1 000	1 065	1 100	1 235	
Nurse midwives, Grade B	2 382	2 690	3 000	3 400	3 720	4 423	
Village midwives	700	775	850	910	960	1 400	

a/ Third Five year plan, requirements for 1981.

Table 11: Output of health manpower

	1973/74	1974/75	1975/76	1976/77	1977/78
Medical doctors	53	58	57	49	42
Assistant medical officers	24	-	33	-	35
Medical assistants	91	120	171	163	171
Rural medical aids	95	91	259	347	301
Nurses, Grade A	59	66	81	106	105
Nurses, Grade B	355	415	366	346	383
Nurse midwives	269	298	375	354	330
Health auxiliaries	30	34	44	45	45

Source: Government of the United Republic of Tanzania, The Economic Survey, 1977-78, p. 36 1979 and p. 114-15.

(i) Supply of pharmaceuticals

All pharmaceutical imports into the United Republic of Tanzania are carried out by the Government through two centralized agencies - the Central Medical Stores operating under the Ministry of Health and the National Pharmaceutical Company, a para-statal organization operating under the Ministry of Trade. Over 90 per cent of the country's total consumption of pharmaceuticals is imported through these two agencies as finished products mainly from the United States of America and Western Europe. Local firms are currently able to produce less than 10 per cent of the total consumption and their manufacturing activities are limited to formulation and packaging using imported raw materials.

Taking advantage of the low level of development of the United Republic of Tanzania's regulatory control on pharmaceutical activities, transnational firms are currently able to place a large variety of their branded products on the market (public and private sector) through intensive promotion efforts.

(ii) Drug legislation and regulatory control

Drug control in the United Republic of Tanzania is based on the Pharmaceutical and Poisons Act of 1978. This legislation gives over-all responsibility for regulatory control to the Minister of Health with the assistance of a Pharmacy Board which assumes delegated powers and responsibilities for regulating the professional activities of pharmacists as well as all dealings in pharmaceuticals. These regulations involve in particular:

(a) Control of pharmaceutical manufacturing through licencing such activities, including registration of premises. Such control includes regulations on manufacturing standards, inspection of premises and sampling and analysis of products at any manufacturing stage;

(b) Registration and licencing of importers and wholesalers of pharmaceuticals and poisons;

(c) Registration of pharmacists and licencing of pharmaceutical retail shops;

(d) Establishment of categories and lists of poisons;

(e) Registration of imported pharmaceuticals;

(f) Control of labelling and advertisement of pharmaceutical preparations.

The Pharmaceuticals and Poisons Act of 1978 does not, however, have sufficient scope to cover all the aspects of drug control discussed in this study; neither does the Ministry seem to have the adequate resources, particularly in terms of skilled manpower, to bring about adequate control.

(iii) Quality control facilities and procedures

The United Republic of Tanzania does not at the moment have a national central drug quality control laboratory. Instead, the Government uses as in the case of Kenya, a government chemist for checking certain fraudulent practices in general.

Under such circumstances, the country is not equipped to ensure the quality, efficacy and safety of all imported as well as locally produced drugs through the application of an adequate level of pre-market screening and post-market surveillance of drugs.

(iv) Product selection

As far as the public sector is concerned, serious concern about irrational usage of drugs, both in terms of medical and economic considerations, has led to the establishment by the Ministry of Health in 1974 of a National Formulary containing a total of 256 drugs, about 80 of which are restricted (to be issued only on prescription by a consultant or a specialist for an individual patient).

The Pharmaceutical and Supplies Committee is made up of seven members of which five are medical doctors and one is a pharmacist. The Committee evaluates, appraises and selects, from among numerous available drugs and dosage forms, those that are most useful in patient care.

However, based on observations made during the present brief study mission, some major transnational corporations mainly based in the United Kingdom, the Federal Republic of Germany, the United Republic of Tanzania and Switzerland, account for over 50 per cent of drug imports, and many of their expensive brand drug items have managed to create overexpenditures on drugs at many public sector hospitals including the Muhimbili Medical Centre, the leading referal hospital.

Undoubtedly this is a situation that calls for stronger efforts by both the Government and the medical profession to ensure implementation of the said National Formulary by standing fast, in particular, against arm-twisting sales promotion tactics.

(v) Procurement, distribution and production

Pharmaceutical supplies in the United Republic of Tanzania are procured and distributed by two central agencies, the government Central Medical Stores and the para-statal National Pharmaceutical Company.

(a) Central Medical Stores, located in Dar-es-Salaam is responsible for procuring and distributing drugs and medical supplies used in government health institutions. Voluntary agencies, such as missions, are permitted to purchase their supplies from the Stores on "come and get it" basis and are charged a 10 per cent margin on landed cost. The charge to government institutions is 5 per cent on landed cost to cover transport costs (from port to warehouse) and packaging expenses. In terms of distribution the Stores assumes responsibility for transporting supplies to its four branches covering the south western lake zone and southern highlands regions. Having no transport of its own it has to depend on rented services. In terms of managerial skill, the Stores is headed by an administrator who is not a qualified pharmacist. He is assisted by a junior pharmacist and various unskilled auxilliaries who lack adequate training in stores management.

(b) The Stores purchases its supplies via international tender (through the interministerial Central Tender Board) on a yearly basis. Although tender quotations are for 100 million shillings, actual allocations for the Stores have never exceeded 40 million shillings per year. This, coupled with inadequacies in managerial skills, has created problems of supply shortages for the Stores. According to the present management, the current procedure used by the Stores in meeting these problems is by making good use of its authorization to make interim purchases without tender, provided the cost of the individual item to be bought does not exceed 50,000 shillings. Another helping factors is said to be the Government's current system of decentralized financing in which each one of the country's regions has its own drugs and medical supplies budgetary allocations and is therefore able to take steps to optimize drug expenditure.

(c) The National Pharmaceutical Company, a para-statal agency based at Dar-es-Salaam, is responsible for procuring pharmaceutical and medical supplies for the private sector. General observations during the present study mission have indicated that a number of major transnationals, such as Hoechst, Roche, Sandoz, etc. are strongly active in both private and public sector health institutions through this company.

(d) As noted earlier, the contribution of local production to total consumption in the United Republic of Tanzania is less than 10 per cent. The local pharmaceutical industry is currently composed of three small formulation plants, Keko Pharmaceutical Plant operating under the Ministry of Health; Mansoor Daya Chemicals Ltd. (private); and Khanbai Pharmaceuticals (private). A fourth plant, the Mabilo Vaccine Institute is engaged in the production of sera and vaccines.

Table 12: Local production output (in shillings)

Production plant	1976-77	1977-78	1978-79	1979-80
Keko	1,000,000	4,000,000	5,000,000	7,200,000
Mansoor Daya	-	-	-	-
Khanbai Pharmaceuticals	-	-	-	-
Mabilo Vaccine Institute	100,000	124,000	200,000	240,000
Total	1,100,000	4,124,000	5,200,000	7,440,000

Source: United Republic of Tanzanis; Estimates of public expenditure vol. II, supply votes, sect. II, p. 253.

(e) As provided in the third five year plan, the United Republic of Tanzanian Government has, in co-operation with UNIDO, completed feasibility studies for establishing a large pharmaceutical production plant in Arusha. Construction has already started and the factory is expected to meet 40 per cent the country's pharmaceutical supply requirements.

Table 13: Local production output (in shillings)

Production plant	1976-77	1977-78	1978-79	1979-80
Mabilo Vaccine Institute	100,000	124,000	200,000	240,000
Keko pharmaceutical plant	1,000,000	4,000,000	5,000,000	7,200,000
Total	1,100,000	4,124,000	5,200,000	7,440,000

Source: United Republic of Tanzania; Estimates of public expenditure vol. II; Supply votes, sect. II, p. 253.

(f). The United Republic of Tanzania has joined eight other countries of East, Central and Southern Africa (Zambia, Kenya, Uganda, Botswana, Swaziland, Mauritius, the Seychelles and Lesotho) in forming the region's Commonwealth Health Secretariat with the aim of taking a common stand against the abusive and harmful business practices of pharmaceutical transnationals in general and for bulk purchase of essential drugs on regional basis in particular.

Although this is a good step in the right direction, the United Republic of Tanzania still needs to establish an adequate regulatory mechanism for pre-market screening of drugs and for controlling the business practices of transnationals using, at least as a start, the Certification Scheme recommended by WHO.

(d) The Sudan

(i) Health services

The medical and pharmaceutical branches of the Sudan's health services aim at meeting the health needs of some 17 million people distributed over an area of 2.5 million km^2. The country is divided into 12 provinces each coming under a provincial medical officer responsible for all aspects of curative and preventive medicine.

Table 14: Health facilities (1978)

Facility	Country total	Pop/facility ratio
Hospitals	150	113 000
Beds	16 869	1 000(b)
Health centres	213	80 000
Dispensaries	766	22 000
Dressing stations	1 851	9 000
Primary health care units	460	37 000
Pharmacies	1 505(b)	

Source: Statistics Division, Ministry of Health, Khartoum. Unpublished data.

(a) = 1975 data

(b) = Ratio for Khartoum is 431 and 1,420 for the provinces.

Table 15: Health personnel (1978)

Category	Total
Doctors	2 165(a)
Medical assistants	2 518
Nurses (qualified)	322
Nurses (lower grade)	12 496
Health visitors	434
Sanitary overseers (all categories)	11 728
Public health officers	247
Public health inspectors	102
Technicians	358

Source: See Table 14.

(a) Population per doctor ratio for the country as a whole, Khartoum and the provinces is 7,800, 1,000 and 19,000 respectively.

Although government expenditure on health services has increased from L.Sd.15 million in 1971/72 to over L.Sd. 30 million in 1978/79, the Sudan is still faced with many basic problems in meeting the health needs of the majority of its population. These problems are, as in the case of the other Af African countries surveyed by this mission, tied up with basic problems of socio-economic development in which limited financial and manpower resources as well as inadequacies in planning and management are contributing to the low and uneven distribution of health facilities and personnel with a disproportionally high concentration in urban areas.

(ii) Pharmaceuticals

In so far as the pharmaceutical supply system is concerned, the Sudan still lacks the effective national policy and management required to allow the optimal delivery of pharmaceutical services to the majority of its population. The major deficiencies of the existing pharmaceutical supply system may be characterized briefly as follows:

(a) Large dependence on imports to meet the country's pharmaceutical supply needs, with local production having a low impact on total consumption;

(b) Lack of policy and mechanisms for co-ordinating the various aspects of the present pharmaceutical supply system to ensure the optimal delivery of services;

(c) Lack of policy on product selection to check the undue proliferation of duplicative drugs on the market and to ensure cost effectiveness in the public sector procurement system and in the local production of pharmaceuticals;

(d) Inadequacies in the management of the existing centralized public sector agency for drug procurement, storage and distribution to forestall shortages of essential pharmaceutical supplies;

(e) Lack of financial and trained manpower resources to meet existing difficiencies and gear the present system towards an adequately developed pharmaceutical supply system;

(f) Inadequate control of the business practices of pharmaceutical transnationals, as a result of which the number of duplicative drug types registered in the country in 1975 was estimated to be of the order of 10,000 with more than 250 private firms competing in their marketing.

(iii) Drug legislation and regulatory control

Existing legislation dealing with regulatory control of drugs is based on the Pharmacy and Poisons Act of 1963 according to which the Central Board of Public Health is empowered to assume over-all responsibility for regulatory control in:

(a) Registering and licencing individuals and establishments engaged in the manufacture, import, wholesale distribution and retailing of pharmaceutical products;

(b) Establishing various categories of poisonous drugs lists as well as controlling their uses;

(c) Establishing subregulations based on the said Act, when appropriate;

Under its terms of reference, the Board is applying the following pre-market screening criteria to determine the eligibility of new drugs for registration:

(a) Compliance to a certification scheme similar to the one proposed by WHO;

(b) Prior submission of clinical trial documentation from country of origin followed by a similar clinical trial in the Sudan;

(c) Prior approval for any price increase;

(d) Proof of the new drug's therapeutic advantage over existing equivalent products. This particular requirement imposes restrictions on the number of brand-name products coming under a particular generic classification.

(iv) Quality control

In addition to the application of the above schemes of quality control on new drugs to be imported, the Sudan is also making some attempts to control quality through a range of tests carried out at the State Laboratory affiliated to the Ministry of Health.

(v) Product selection

The Sudan has yet to establish an effective system of product selection through a restricted list of essential drugs similar to the model proposed by WHO to check the preliferation of drug types on its market and to ensure, in terms of cost benefit considerations, the procurement, production and use of drugs within its public sector health service system. To date however:

(a) Even the National Formulary published in 1979 after considerable effort in order to limit the variety of drugs to be imported and to serve as a guide for prescribers in selection the best drugs for patients, is not mandatory;

(b) Because of the lack of adequately trained staff in management, the Central Medical Stores, responsible for the procurement and distribution of 80 per cent of the requirements of public sector health facilities, is still unable to forestall shortages of essential pharmaceutical supplies;

(c) The shortage of qualified staff and inadequate supervision of insufficiently trained personnel dispensing drugs at the various levels of health delivery facilities perpetuate irrational drug use.

(vi) Domestic production[14/]

Domestic pharmaceutical production in the Sudan is, as in the other countries surveyed by this mission except Egypt, at a relatively low level of development. The three existing pharmaceutical formulation plants are:

(a) A government-owned plant at Khartoum established in 1968, which produces some dosage forms, mainly tablets, some liquids and sterile gauze, mainly through licence arrangements with the Egyptian Nile Pharmaceutical Company and supplies chiefly the Ministry of Health;

(b) The Pharmaceutical Industry and Cosmetics Laboratory in Khartoum established in 1963, which operates as a joint venture between foreign and Sudanese private share holders and produces a small range of dosage forms such as tablets, ointments, liquids, powders and cosmetics;

(c) Nicholas Sudan Ltd. which operates as a subsidiary of Aspro Nicholas of the United Kingdom and Australia and is limited to the production of Aspro and medicated face cream;

These domestic pharmaceutical production units operate in the absence of a policy for product selection as well for the integration and co-ordination of efforts to allow them to make useful contribution to the rational development of the country's pharmaceutical supply system. The impact of their production to the country's total consumption has remained low, and information obtained from the Ministry of Health indicates that they will need to make stronger efforts to improve the quality and presentation of their products to make them competitive with imported preparations.

(vii) Pharmaceutical education facilities

Although the Sudan has three universities, only one of them, the University of Khartoum, is equipped for training and graduating qualified pharmacists. Its output at present stands at 40 pharmacists per year.

14/ The present mission was not able to visit the Sudan's existing pharmaceutical production facilities. The information presented here is based upon enquiries made at the Ministry of Health Statistics Division, and upon reference to the following studies undertaken by other missions:

(a) Pharmaceuticals in the Sudan, Dr. Vojtech (WHO Consultant, 1976); and (b) Integrated development of the pharmaceutical industry in the North African region, Dr. Ali Aboul Enein (President Chemical Industry Development, Cairo, 1979.

One of the grave difficiencies of the country's present pharmaceutical supply system is shortage of trained pharmacists. One important factor that serves to perpetuate this unsatisfactory situation is the fact that, because of the unattractive conditions of employment in government service, most of the country's pharmacists end up obtaining employment in the private sector dominated by transnationals which are able to offer better employment opportunities and make good use of such trained personnel in promoting their brand-name drug products on the country's market. This problem is not something peculiar to the Sudan but an essentially common phenomenon in most of the countries surveyed by this mission and which should, in view of its gravity, beggiven serious attention by the Governments concerned.

(e) Egypt

(i) Health services

Among the six African countries surveyed by this mission, Egypt has attained the highest level of development in terms of both its over-all health services and its pharmaceutical supply system.

The country's general health situation is characterized by lower incidence of diseases than most of the African countries except North Africa. Accordingly, and with more than 3,000 hospitals, 21,000 doctors and 3,500 pharmacies throughout the country, Egypt has achieved a health infrastructure that has allowed it to deliver a relatively high level of health care to the population.

Table 16: Health infrastructure

	1966	1970	1972	1973	1974
Hospitals	2 617	2 938	3 071	-	-
Beds	66 862	70 932	74 596	-	-
Physicians	13 625	11 848	15 198	17 240	21 247
Pharmacists	3 758	5 371	6 243	7 854	-
Midwives	8 446	11 054	-	-	-
Nurses	6 496	9 040	-	-	-

Source: Country report of the ECA/UNIDO Chemical Industry Development Programme Mission to Egypt, 1979.

Table 17: Total health manpower development

Year	1952	1962	1967	1972	1978
Manpower	1 100	6 300	10 000	17 400	22 000

Source: Development of the Drug Industry in Egypt, Dr. Salah El Din, 1979.

(ii) Pharmaceuticals

Prior to 1952, the Egyptian market was a fertile ground for exploitation by pharmaceutical transnationals. Such firms were, in the absence of effective policy and regulatory control, able to flood to Egyptian market with some 20,000 of their duplicative brand-name drugs. Under such circumstances and with the low level of development of its domestic pharmaceutical industry, Egypt had to depend on imports to meet as much as 90 per cent of its pharmaceutical supply needs.

Since 1952, a series of basic steps was taken by the Government to improve the country's unsatisfactory pharmaceutical supply situation and lay the foundation of an adequately developed pharmaceutical supply system. Through such efforts, Egypt has been able to achieve a relatively advanced stage of development in the pharmaceutical sector. This is evidenced by the fact that the total number of imported pharmaceutical brand products has been brought down to about 600 and the contribution of domestic production to total consumption raised to over 82 per cent in 1979.

(iii) Consumption

Total consumption of pharmaceutical products in Egypt has increased from LE 4.8 million in 1952 to LE 170 million in 1978, the contribution of domestic production being LE 133.4 million or about 80 per cent. Consumption in terms of value per capita increased from LE 0.22 in 1952 to LE 5.0 in 1979.

The development of total consumption, local production and the proportion of local production to total consumption is shown under Table 18.

Table 18: Total consumption and local production of pharmaceutical

Year	Total consumption LE	Local production LE	Imports LE	Local production / Total consumption (percentage)	Public sector share in total consumption (percentage)
1952-53	4.8	0.5	4.3	10	-
1962-63	22.5	12.0	10.4	53	-
1965-66	35.0	26.6	8.4	76	-
1971	52.5	45.3	7.2	86.3	-
1972	55.1	48.2	7.0	87.3	-
1973	62.30	55.0	7.3	88.2	-
1974	72.8	62.9	9.9	86.0	-
1975	88.4	74.3	14.1	84.0	-
1976	112.5	94.5	17.9	84.0	77.1
1977	147.9	122.0	25.9	82.5	73.8
1978	178.5	148.0	37.4	82.9	73.2
1979	204.0	166.9	-	81.8	71.3

Source: Development of the Drug Industry in Egypt by Dr. Salah El Din, M. Shaddad, Production Manager, Arab Drug Co., Cairo, 1979.

(iv) Local distribution

The system applied for importing and distributing finished dosage forms as well as inputs and outputs of domestic pharmaceutical production is as follows:

(a) The State-owned Egyptian Pharmaceutical Trading Company in Cairo, established in 1965, is responsible for distributing about 60 per cent of locally produced drugs as well as of some 600 imported preparations to public sector health facilities through a chain of 45 medical stores.

(b) The private sector, containing 3,500 pharmacies, is supplied directly by domestic manufacturers as well as by various agents of foreign manufacturing firms for imported pharmaceutical specialities. The Government charges an import duty of 23 per cent on c.i.f. prices for private sector imports of pharmaceutical preparations.

(c) The State-owned El Gomhouria Co., established in 1962, is responsible for supplying pharmaceutical chemicals and medical appliances to the domestic pharmaceutical industry.

(v) Regulatory control

Existing policy for regulatory control provides that no drug is allowed to be imported or manufactured locally before meeting the registration requirements of the Egyptian Ministry of Health. Accordingly, an application must be submitted to the Department of Pharmacy together with the following particulars:

(a) The required number of samples in original package;

(b) Certificate of "free sale" similar to the "Certification Scheme" recommended by WHO;

(c) Formula in detail;

(d) Certificate of analysis and method of analysis;

(e) Certified scientific reports and information related to the pharmacology, toxicity, side effects and contra-indications of the drug;

(f) The final responsibility for clearing the drug rests upon the Technical Secretariat for Drugs which evaluates the drug in terms of quality, efficacy, safety and price.

(vi) Quality control

Through the establishment of the National Organization for Drug Control and Research, Egypt has been able to achieve an efficient system of quality control for both imported and locally produced pharmaceutical products. In the course of exercising its responsibility in quality checking and deciding on the marketability of any pharmaceutical product, the Organization pays particular attention to antibiotics, I.V. solutions, catgut and all products for export.

With the domestic pharmaceutical industry also having achieved a well organized internal quality control system, Egypt is now paying more attention to the implementation of a system of quality control in which the local industry should assume full responsibility for guaranteeing the quality, efficacy and safety of its drugs. Accordingly, large funds were allocated by the pharmaceutical industry in 1978 for achieving the said objectives.

(vii) Product selection

To date, Egypt has not established a restricted list of essential drugs based on, or similar to the model proposed by WHO, although public sector health facilities are required to use the official drug list adopted by the Ministry of Health.

While strong efforts in drug control have brought about a significant reduction in the number of duplicative brand-name drug products on the market the fact that the Government's "open door policy" authorizes private enterprises to import and market pharmaceutical specialities led to a two fold increase in drug imports between 1975 to 1978. Undoubtedly this has contributed to the recent significant increases in total consumption and reduction in the contribution of local production to total consumption (see table 18).

(viii) Domestic pharmaceutical production

As noted earlier, the first clear signs indicating Egypt's movement towards self-reliance in pharmaceuticals appeared in 1962/63 when the Government was able to increase the contribution of the domestic industry to the country's over-all demand for drugs from 10 to 53 per cent. This contribution has been increased further to about 32 per cent in 1979.

Currently, Egypt's domestic pharmaceutical industry is composed of 13 firms, nine of which are state-owned and four are joint ventures with transnational corporations.14/ Seven of the public sector firms are engaged in the formulation of all known dosage forms, one in the production of basic chemicals and finished pharmaceutical products in bulk, ant the last one in the production of plastic, aluminium and paper packing materials. These firms are:

14/ The capital shares of the four foreign subsidiaries are owned to the extent of 60 per cent by their respective parent companies and the rest by private Egyptian shareholders.

(a) Private sector, joint venture firms:

(i) Pfizer (1960)

(ii) Hoechst (1960)

(iii) Swiss Pharma of Cuba-Geigy, Sandoz and Wander (1965)

(iv) Squibb (1979)

(b) Public sector formulation plants:

(i) Misr Co. (1939)

(ii) Memphis Co. (1940)

(iii) C.I.D. Co. (1947)

(iv) El Nil Co. (1962)

(v) Alkahira (1962)

(vi) Alexandria Co. (1962)

(vii) Arab Drug Co. (1963)

(c) Public sector basic pharmaceutical chemicals production plant:

(i) El Nasr Co. (1962)

(d) Public sector packing materials production plant:

(i) Pharmaceutical Packing Co. (1964).

The four joint venture firms are engaged mainly in the production of trade marked specialities of their parent (TNC) companies and were, in 1979, able to produce only about 14 per cent of Egypt's total pharmaceutical consumption.

The seven public sector formulation plants rely to a large extent in the production of specialities including transnational trade marked products manufactured locally under licence. Some of these firms, such as C.I.D. and Memphis are characterized by a long tradition of research and development and an effective exploitation of local raw materials. C.I.D. is the largest formulation plant in Egypt in terms of manpower (including skilled staff), manufacturing output, and product differentiation.

El Nasr Co. is engaged in the bulk production of pharmaceutical chemicals for the local industry as well as in the formulation of dosage forms. Currently, it has sections for the production of fine and analytical chemicals, industrial enzymes, i.v. fluids and solutions, blending antibiotics, pharmaceutical formulation into tablets, capsules, etc. and plastic disposable products.

Expansion programmes include the establishment of an antibiotic fermentation plant and a synthesis unit.

The Pharmaceutical Packing Co. was established in 1962 to serve the local industry but has, to date, been unable to meet all its requirements for packing materials. Empty hard gelatin capsules are still imported in huge quantities (100 million capsules per year). The local industry is also largely dependent on imports for neutral glass ampoules and vials as well as glass bottles of various sizes and types.

The assumption of responsibility for providing immunological preparations for preventive health care by the Government may be traced back to 1897 when production of small pox vaccine had started. Coverage of all other vital products including plasma, blood derivatives and anti T.B. vaccine was achieved in 1948 and over-all responsibility in this field was given to the Egyptian General Organization for Biological Products in 1972. Egypt has not only achieved complete self-reliance in immunological preparations but is also able to export some of these products.

On the whole, the pharmaceutical industry in Egypt has made a remarkable progress in increasing its contribution to the country's total consumption of finished drugs from 10 per cent in 1953 to 53 per cent in 1963 and 82 per cent in 1979 (see Table 19). This percentage is expected to go ven higher in the next few years, 86 per cent being the target for 1981 alone.

That national firms have already done well in competing with foreign firms on the domestic market is made evident by the fact that out of the domestic industry's share of 82 per cent in total consumption in 1979 national firms accounted for 71 per cent while transnational subsidiaries accounted for only 14 per cent. National firms also lead transnational suppliers for specialities in a number of major therapeutic categories as indicated in Table 19.

Table 19: Number of specialities in the Egyptian market (1979)

Therapeutic category	Locally produced	Imported
Analgesics and antirheumatics	94	16
Antibiotics	145	44
Antimalarials	5	-
Anti T.B. and antileprotics	10	6
Vitamins	123	3
Psychopharmaceuticals	84	65

Source: Dr. Salah El Din's report (1979), p. 26.

However, pharmaceutical transnational corporations are still able to maintain an upper hand in the supply of basic and intermediate pharmaceutical chemicals as well as machinery, equipment and packing materials required by the local industry. Production of most pharmaceutical chemicals at El Nasr Co. starts from intermediates imported at relatively high prices, thus entailing high production costs and high retail prices. In order to strengthen the capabilities of national firms to compete against transnationals and to pave the way towards achieving complete self-reliance in pharmaceuticals, Egypt will need to increase its capability in the chemical industry sector. Most of the organic chemicals required for the synthetic drug industry could be made available at better prices than those supplied by transnationals when Egypt's petrochemical industry becomes fully operational. Similarly, other chemical industry sectors serving as suppliers of raw materials will have to be expanded and the necessary linkages with the local pharmaceutical industry established.

Government policy on foreign investment and its impacts on the growth of the local industry:

Egypt's present policy on foreign investment (Law No. 43 of 1974 as amended by Law No. 32 of 1977) encourages and promotes through various incentives foreign investors in the country's industrial development process with the understanding that Egypt's industry as a whole needs foreign capital and technological know-how to improve domestic output, exploit local resources and expand expand export sales.

Although the said policy allows transnational investors to obtain a high price for their capital, know how and services, the various government bodies responsible for processing and approving foreign investment projects in their respective sectors are trying to ensure that such investment projects are beneficial to development, that the price paid for them is not excessive, that transfer of technology is not subject to transnational restrictive practices and that such projects will not serve to hinder the domestic industry's growth and development through unfair competition by foreign firms. The Technical Secretariat for the Drug Sector is charged with the responsibility of implementing these objectives.

So far, the new approach to foreign investment has had little effect on Egypt's pharmaceutical industry except to increase the number of private sector joint venture firms from three to four in 1978. The movement towards self-sufficiency in pharmaceutical production continues through the Government's comprehensive strategy for an integrated development of its pharmaceutical industry including regulation of drug procurement, distribution, prices, quality control, promotion practices and exports. In each of these areas, decisions are based on plans covering the whole industry.

The role of United Nations Agencies

Among United Nations agencies, UNIDO, UNCTAD and UNCTC in particular, are in a position to assist Egyptiin further developing her pharmaceutical sector activities, particularly in data gathering and in negotiations with transnational corporations to allow adequate assessment of costs and appropriateness of imported technological process and services.

The young national institutions which Egypt has established recently for collecting and disseminating relevant data as well as for assessing and approving foreign investments and technologies 15/ have begun getting assistance from UNIDO. The flow of data from the UNCTC on business practices of transnational corporations should be complimented with adequate advisory services to strengthen Egypt's capabilities in her negotiations with such firms.

(f) Ghana

(i) General health situation

The health status of the people of Ghana, as measured by life expectancy at birth, causes of morbidity and mortality and vital rates, is very low compared to that of developed countries. Thirty per cent of recorded deaths in the country are due to infections and parasitic diseases such as malaria, tetanus, respiratory and diarrhoeal diseases. Among children under 5 years, 70 per cent of deaths are due to such diseased usually aggravated by malnutrition. Poor coverage of health services, especially in the rural areas, is the key element among numerous factors underlying the poor health status of the population.

Although the country's health care system provides a hierarchy of institutions developed on a regional basis, with health posts and health centres serving as the first contacts with the health services and district hospitals as second level contact, because of various basic inadequacies of the system related to coverage, poor and unequitable distribution of services, the rural population is unable to obtain adequate health care.

Table 20: Health institutions in Ghana, 1967 and 1974

Health Institutions	1967	1974
Hospitals (public sector)	52	64
Hospitals (missions)	33	33
Health Centres	45	58
Health Posts	9	60

Source: Ghana's five-year development plan, 1975/76-1979/80

15/ The General Organization for Foreign Investment under the Ministry of Economy acts as a source of data on transnationals, and the General Organization for Industrialization is responsible for technical assessment of foreign collaboration.

Table 21: Health manpower resources

Category	1952	1973	Percentage increase
Physicians	152	951	525.7
Dental surgeons	6	30	400.0
Pharmacists	256	533	110.2
Nurses	990	6 153	521.5
Midwives	362	4 932	11 262.4
Laboratory technicians	-	276	-
Sanitarians	110	260	136.4

Source: Ibid.

Table 22: Distribution of doctors in the public and private sectors (1973)

	Total number of doctors	percentage
Accra	380	36.8
Communities with a population above 20,000	313	30.4
Communities below 20,000	338	32.8

Source: Ibid.

Thus, it is evident that the large increase in health personnel between 1952 and 1973 did not enlarge their equitable distribution to the population. Instead, 77 per cent of all pharmacists remained in towns with a population of 20,000 and above and while the national average of doctor population ratio stood at 1/10,000 the ratio for some region remained as low as 1/10,000. Due to lack of effective measures in improving the country's unsatisfactory health service situation it is estimated that 80 per cent of the population, particularly the rural communities, still remains outside the mainstream of modern medical care.

The major constraints, which have inhibited the extension and effectiveness of the health service system include poor management, planning and evaluation of the health services, inefficient utilization of quantitatively inadequate manpower resources, lack of supporting services, etc.

According to the country's five-year development plan, covering the period 1975/76-1979/80, the long-term objective of the health sector is to raise the level of health of Ghanaians through a network of health institutions to be distributed as widely as possible. The Government is to emphasize expansion of the primary health care segment in particular by extending the distribution of health centres and health posts in order to achieve adequate coverage of the rural population by:

- hospital construction and modernization
- endemic disease control in all parts of the country
- national nutrition survey
- training of health personnel of all categories
- construction of various regional medical stores as well as strengthening of existing facilities
- expansion of domestic public sector pharmaceutical production
- establishment of a centre for research of local herbs for curative purposes, etc.

(ii) Pharmaceuticals

The fundamental problems and major constraints characterizing Ghana's existing health services are naturally carried over to the pharmaceutical service system. The main difficiencies of this sector may be summarized briefly as follows:

(a) Quantitative and qualitative inadequacy of the existing pharmaceutical services in meeting the needs of the majority of the country's population for essential drugs. At present 80 per cent of the population have no access to modern drugs;

(b) Large dependence on imports to meet national drug requirements. The country's largest domestic pharmaceutical production plant, GIHOC Pharmaceuticals, is able to satisfy only 19.4 per cent of the country's market for drugs;

(c) Lack of effective policy and mechanisms for co-ordinating and integrating the various components of the present pharmaceutical supply system for ensuring the optimal delivery of services;

(d) Lack of policy on product selection to check the undue proliferation of duplicative drugs on the private market and to ensure cost effectiveness in the public sector drug procurement and distribution system as well as in local production and in drug usage;

(e) Lack of adequate financial, manpower, planning and management resources for ameliorating existing difficiencies and for establishing an adequately developed pharmaceutical supply system;

(f) Inadequate control of the business practices of pharmaceutical transnationals through the establishment of adequate legislation and regulatory control mechanisms.

(iii) Drug legislation and regulatory control

Existing legislation for regulatory control of drugs as well as persons and establishments engaged in the manufacture, import, wholesale and retail trade in drugs is based on Pharmacy and Drugs Act of 1961. This Act empowers the Pharmacy Board of the Ministry of Health to regulate all activities related to drugs which include:

- regulation of the pharmacy profession
- control of supply of drugs
- control of manufacture and storage of drugs
- control of transport, import and export of drugs

The Act requires that no drug may be imported for marketing in the private sector before being registered by the Pharmacy Board. The main criteria to be met are that a speciality "has not been previously registered under section 54 of the Act" and "that the use of the speciality is likely to prove beneficial". The Act also provides some simplistic criteria dealing with drug quality and registration of pharmaceutical manufacturing establishments.

(iv) Product selection

The inadequacies of existing legislation and regulatory control of drugs are compounded by the lack of an effective system of product selection through the establishment of a restricted list of essential drugs either for checking the proliferation of drug types on the private market or for rationalizing expenditures in public sector drug procurement, distribution and production system as well as for minimizing irrational drug usages.

It is to be noted that even the latest edition of the Ghanaian National Formulary (of 1974-76), prepared with the aim of rationalizing drug usages contain expensive brand-name products to be stocked by the Ministry of Health, and the prescriber is at liberty to prescribe drugs outside the National Formulary, though such items will not be stocked by the Ministry of Health.

(v) Public sector drug procurement and distribution

The Ghana Supplies Commission is responsible for the pharmaceutical supply requirements of public sector health institutions. Supplies are purchased via international tender on a yearly basis through a tender committee composed of qualified professionals. Unforeseen depletion of stock is met through the application of a "quick" quotation system.

The Central Medical Stores is responsible for stocking and distributing medical supplies for public sector health facilities through its existing branch depots.

In order to meet existing inadequacies of the Stores, the Government has, based on its present five-year development plan, committed itself to the construction of new stores and improvement of existing facilities with the aim of meeting the requirements of all regions of the country.

(vi) Domestic production

Ghana's domestic pharmaceutical industry is still at a relatively low level of development. Of the existing three pharmaceutical formulation plants, only the pharmaceutical division of GIHOC (the Ghana Industrial Holding Company), a public sector firm, makes a significant contribution to the country's total consumption of drugs, amounting in 1978 to a mere 19.4 per cent of its pharmaceutical needs through imports.

In 1978, GIHOC Pharmaceuticals was engaged in the formulation of a small range of products in the following forms and quantities;

tablets - 50 million

capsules (hard golatin) - 1 million

ampoules - 10 million

While 80 per cent of the plant's outputs is supplied to the Ministry of Health and the rest to the private market, at no point has GIHOC Pharmaceuticals, been able to meet the Ministry's requirement for drugs because of limitations in production capacity and shortage of funds for procuring raw material inputs.

Based on the Government's five-year development plan, GIHOC Pharmaceuticals is to undertake an expansion programme aimed at increasing production on existing lines as follows:

- tablets: from 50 million to 2 000 million
- capsules: from 1 million to 100 million
- ampoules: from 10 million to 25 million

New lines to be introduced are:

- 5 million litres of creams and ointments
- 3 million bottles of aerosols
- 3 million vials
- 100 000 litres of syrups
- 100 000 litres of suspensions

This is expected to raise GIHOC pharmaceuticals share of the drug market to about 60-70 per cent by 1990.

All quality control checking is carried out at the National Central Laboratory, which is also responsible for checking the quality of all imported drugs prior to their registration.

(vii) Medical education

There is an acute shortage of medical and paramedical personnel in Ghana owing to the limited training facilities in the country. By establishing the School of Medical Sciences at the University of Science and Technology as well as the Centre for Public Health at the Korle Bu Teaching Hospital, in addition to the Ghana Medical School at Legon, the Government hopes to increase the output of medical doctors as well as paramedical personnel and medical technologists needed for improving the country's health services.

(viii) Traditional medicine[16/]

Traditional medicine in Ghana is, as in all African countries, a very important element in the health care of the people. The majority of the people of Ghana live in rural and outlying areas beyond the reach of modern medical facilities where traditional healers are the only means for needed health care and advice.

In the light of this situation and the knowledge in particular that many of the herbs used by these healers have useful medicinal properties, the analysis of widely used traditional herbs has become the major concern of the Institute of Scientific Research into Plant Medicine. The Institute is encouraging research aimed at compilation of materia medica on African medical plants. Research into the medicinal properties of various herbs growing in West Africa is also being undertaken both at the University of Ghana, Legon, and at the Faculty of Pharmacy of the University of Science and Technology in Kumasi. It is hoped that these moves by institutions of higher learning and the efforts of the Institute of Scientific Research into Plant Medicine will lead to a health care system that will accomodate traditional medicine in Ghana.

16/ Traditional Healing, Ghana Today, No. 13 published by the Ghana Information Service.

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